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PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 29 September 1999 (29.09.99)	
International application No. PCT/US99/00835	**Applicant's or agent's file reference** 19601-1-2PC
International filing date (day/month/year) 13 January 1999 (13.01.99)	**Priority date** (day/month/year) 14 January 1998 (14.01.98)
Applicant VARDI, Gil, M. et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

13 August 1999 (13.08.99)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer S. Mafla
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

Roger Barrett

TOWNSEND & TOWNSEND & CREW

Townsend and Townsend and Crew

PCT

JUL 13 2000

To: JAMES M. HESLIN
TOWNSEND AND TOWNSEND AND CREW LLP
TWO EMBARCADERO CENTER, 8TH FLOOR
SAN FRANCISCO, CALIFORNIA 94111-3834

00 JUN 30 AM 9:59

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NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing *(day/month/year)*	26 JUN 2000
Applicant's or agent's file reference: 19601-1-2PC	IMPORTANT NOTIFICATION

International application No.	International filing date *(day/month/year)*	Priority Date *(day/month/year)*
PCT/US99/00835	13 JANUARY 1999	14 JANUARY 1998

Applicant: ADVANCED STENT TECHNOLOGIES, INC.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

7-14-00

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	PAUL PREBILIC
Facsimile No. (703) 305-3230	Telephone No. (703) 308-2905

Form PCT/IPEA/416 (July 1992)*

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 19601-1-2PC	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US99/00835	International filing date *(day/month/year)* 13 JANUARY 1999	Priority date *(day/month/year)* 14 JANUARY 1998
International Patent Classification (IPC) or national classification and IPC IPC(7): A61F 2/06 and US Cl.: 623/1		
Applicant ADVANCED STENT TECHNOLOGIES, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets.

   [✓] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

   - I [X] Basis of the report
   - II [ ] Priority
   - III [X] Non-establishment of report with regard to novelty, inventive step or industrial applicability
   - IV [ ] Lack of unity of invention
   - V [X] Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI [ ] Certain documents cited
   - VII [ ] Certain defects in the international application
   - VIII [ ] Certain observations on the international application

Date of submission of the demand	Date of completion of this report
13 AUGUST 1999	08 MAY 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer PAUL B. PREBILIC Telephone No. (703) 308-2905

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application.

☒ claims Nos. 5-21

because:

☐ the said international application, or the said claim Nos. _ relate to the following subject matter which does not require international preliminary examination *(specify)*.

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 5-21 are so unclear that no meaningful opinion could be formed *(specify)*.

Multiple dependent claims which depend from other multiple dependent claims are not examinable under United States practice because they are too indefinite to determine the scope thereof.

☐ the claims, or said claims Nos. _ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US99/00835

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	NONE	YES
	Claims	1-4	NO
Inventive Step (IS)	Claims	NONE	YES
	Claims	1-4	NO
Industrial Applicability (IA)	Claims	1-4	YES
	Claims	NONE	NO

2. citations and explanations (Rule 70.7)

Claims 1-3 lack novelty under PCT Article 33(2) as being anticipated by Taheri (5,617,878).

Claims 1-4 lack novelty under PCT Article 33(2) as being anticipated by Venbrux (5,443,497).

---------- NEW CITATIONS ----------

US 5,443,497 A (VENBRUX) 22 AUGUST 1995, see the entire document.

International application No.
PCT/US99/00835

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

I. BASIS OF REPORT:

5. (Some) amendments are considered to go beyond the disclosure as filed:
NONE

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

TOWNSEND & TOWNSEND & CREW

PCT 20 AM 9:17

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WRITTEN OPINION

(PCT Rule 66)

To: JAMES M. HESLIN
TOWNSEND AND TOWNSEND AND CREW LLP
TWO EMBARCADERO CENTER, 8TH FLOOR
SAN FRANCISCO, CALIFORNIA 94111-3834

Date of Mailing *(day/month/year)*	14 DEC 1999
Applicant's or agent's file reference: 19601-1-2PC	**REPLY DUE** within TWO months from the above date of mailing: 2-14-00

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US99/00835	13 JANUARY 1999	14 JANUARY 1998

International Patent Classification (IPC) or both national classification and IPC
IPC(6): A61F 2/06; and US Cl.: 623/1

Applicant
ADVANCED STENT TECHNOLOGIES, INC.

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I [X] Basis of the opinion
- II [ ] Priority
- III [X] Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
- IV [ ] Lack of unity of invention
- V [X] Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI [ ] Certain documents cited
- VII [ ] Certain defects in the international application
- VIII [ ] Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension., see Rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 *bis*.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 14 MAY 2000

Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer: Patricia Marks PAUL PREBILIC
Facsimile No. (703) 305-3230	Telephone No. (703) 308-2905

DOCKETED

Form PCT/IPEA/408 (cover sheet) (January 1994)

WRITTEN OPINION

International application No.
PCT/US99/00835

I. Basis of the opinion

1. This opinion has been drawn on the basis of *(Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".)*:

[X] the international application as originally filed.

[X] the description, pages 1-15 , as originally filed.
pages NONE , filed with the demand.
pages NONE , filed with the letter of _____.

[X] the claims, Nos. 1-21 , as originally filed.
Nos NONE , as amended under Article 19.
Nos. NONE , filed with the demand.
Nos. NONE , filed with the letter of _____.

[X] the drawings, sheets/~~fig~~ 1-13 , as originally filed.
sheets/~~fig~~ NONE , filed with the demand.
sheets/~~fig~~ NONE , filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

[X] the description, pages NONE

[X] the claims, Nos. NONE

[X] the drawings, sheets/~~fig~~ NONE

3. [ ] This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the ~~Supplemental Box~~ Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:
NONE

WRITTEN OPINION

International application No.
PCT/US99/00835

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application.

☒ claims Nos. 5-21

because:

☐ the said international application, or the said claim Nos. _ relate to the following subject matter which does not require international preliminary examination *(specify)*.

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 5-21 are so unclear that no meaningful opinion could be formed *(specify)*.

Multiple dependent claims which depend from other multiple dependent claims are not examinable under United States practice because they are too indefinite to determine the scope thereof.

☐ the claims, or said claims Nos. _ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _.

WRITTEN OPINION

International application No.
PCT/US99/00835

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims	NONE	YES
	Claims	1-4	NO
Inventive Step (IS)	Claims	NONE	YES
	Claims	1-4	NO
Industrial Applicability (IA)	Claims	1-4	YES
	Claims	NONE	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-3 lack novelty under PCT Article 33(2) as being anticipated by Taheri (5,617,878).

Claims 1-4 lack novelty under PCT Article 33(2) as being anticipated by Venbrux (5,443,497.

---------- NEW CITATIONS ----------

US 5,443,497 A (VENBRUX) 22 AUGUST 1995, see the entire document.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

TIME LIMIT:

THE TIME LIMIT SET FOR RESPONSE TO A WRITTEN OPINION MAY NOT BE EXTENDED. 37 CFR 1.484(D). ANY RESPONSE RECEIVED AFTER THE EXPIRATION OF THE TIME LIMIT SET IN THE WRITTEN OPINION WILL NOT BE CONSIDERED IN PREPARING THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT.

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/06

A1

(11) International Publication Number: WO 99/36002

(43) International Publication Date: 22 July 1999 (22.07.99)

(21) International Application Number: PCT/US99/00835

(22) International Filing Date: 13 January 1999 (13.01.99)

(30) Priority Data:
09/007,265 14 January 1998 (14.01.98) US

(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Applications
US 09/007,265 (CIP)
Filed on 14 January 1998 (14.01.98)
US 08/744,002 (CIP)
Filed on 4 November 1996 (04.11.96)

(71) Applicant *(for all designated States except US)*: ADVANCED STENT TECHNOLOGIES, INC. [US/US]; Suite A, 4070 Nelson Avenue, Concord, CA 94520 (US).

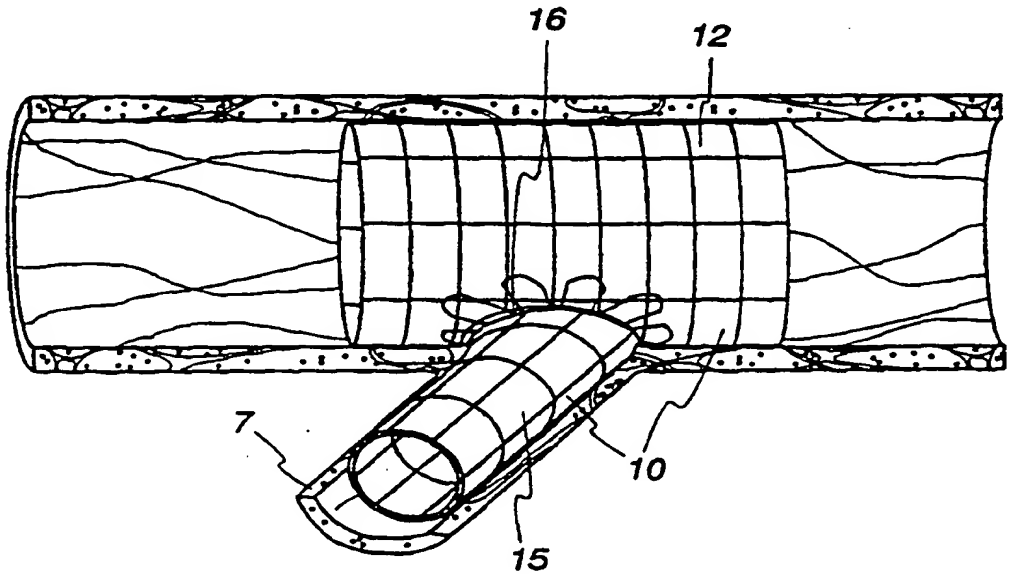
(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: VARDI, Gil, M. [IL/US]; Apartment 1002–B, 333 E. Ontario, Chicago, IL 60611 (US). DAVIDSON, Charles, J. [US/US]; 1311 Sunview Lane, Winnetka, IL 60093 (US). ELAM, Eric [US/US]; 1125 Davis Street #B–3, Evanston, IL 60201 (US). LIN, Stuart [US/US]; 2800 E. Nasa Road One #1307, Seabrook, TX 77586 (US).

(74) Agents: HESLIN, James, M. et al.; Townsend and Townsend and Crew LLP, 8th floor, Two Embarcadero Center, San Francisco, CA 94111–3834 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: EXTENDIBLE STENT APPARATUS



(57) Abstract

The bifurcating double stent apparatus (10) of the present invention comprises a generally cylindrical main stent (12), a generally cylindrical branch stent (15), which are shown as fully dilated in a subject main vessel (8), and a subject branch vessel (7). The main stent (12) is deployed prior to the branch stent (15) which is then aligned with the side opening (16) of the main stent (12), and attached at that location.

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EXTENDIBLE STENT APPARATUS

BACKGROUND OF THE INVENTION

A type of endoprosthesis device, commonly referred to as a stent, may be placed or implanted within a vein, artery or other tubular body organ for treating occlusions, stenoses, or aneurysms of a vessel by reinforcing the wall of the vessel or by expanding the vessel. Stents have been used to treat dissections in blood vessel walls caused by balloon angioplasty of the coronary arteries as well as peripheral arteries and to improve angioplasty results by preventing elastic recoil and remodeling of the vessel wall. Two randomized multicenter trials have recently shown a lower restenosis rate in stent treated coronary arteries compared with balloon angioplasty alone (Serruys, PW et al. New England Journal of Medicine 331: 489-495, 1994, Fischman, DL et al. New England Journal of Medicine 331: 496-501, 1994). Stents have been successfully implanted in the urinary tract, the bile duct, the esophagus and the tracheo-bronchial tree to reinforce those body organs, as well as implanted into the neurovascular, peripheral vascular, coronary, cardiac, and renal systems, among others. The term "stent" as used in this Application is a device which is intraluminally implanted within bodily vessels to reinforce collapsing, dissected, partially occluded, weakened, diseased or abnormally dilated or small segments of a vessel wall.

One of the drawbacks of conventional stents is that they are generally produced in a straight tubular configuration. The use of such stents to treat diseased vessels at or near a bifurcation (branch point) of a vessel may create a risk of compromising the degree of patency of the primary vessel and/or its branches, or the bifurcation point and also limits the ability to insert a second stent into the side branch if the result of treatment of the primary, or main, vessel is suboptimal. Suboptimal results may occur as a result of several mechanisms, such as displacing diseased tissue, plaque shifting, vessel spasm, dissection with or without intimal flaps, thrombosis, and embolism.

The risk of branch compromise is increased generally in two anatomical situations. First, a side branch may be compromised when there is a stenosis in the origin

of the side branch. Second, when there is an eccentric lesion at the bifurcation site, asymmetric expansion can cause either plaque shifting or dissection at the side branch origin. There are reports of attempts to solve this problem by inserting a balloon into the side branch through the struts of a stent deployed in the main branch spanning the bifurcation point; however, this technique carries the risk of balloon entrapment and other major complications (Nakamura, S. et al., Catheterization and Cardiovascular Diagnosis 34: 353-361 (1995)). Moreover, adequate dilation of the side branch is limited by elastic recoil of the origin of the side branch. In addition, insertion of a traditional stent into a main vessel spanning a the bifurcation point may pose a limitation to blood flow and access to the side branch vessel. The term "stent jail" is often used to describe this concept. In this regard, the tubular slotted hinged design of the Palmaz-Schatz intracoronary stent, in particular, is felt to be unfavorable for lesions with a large side branch and is generally believed to pose a higher risk of side branch vessel entrapment where the stent prevents or limits access to the side branch. Id.

One common procedure for intraluminally implanting a stent is to first open the relevant region of the vessel with a balloon catheter and then place the stent in a position that bridges the treated portion of the vessel in order to prevent elastic recoil and restenosis of that segment. The angioplasty of the bifurcation lesion has traditionally been performed using the "kissing" balloon technique where two guidewires and two balloons are inserted, one into the main branch and the other into the side branch. Stent placement in this situation requires the removal of the guidewire from the side branch and reinsertion through the stent struts, followed by the insertion of a balloon through the struts of the stent along the guidewire. The first removal of the guidewire poses the risk of occlusion of the side branch during the deployment of the stent in the main branch.

In general, when treating a bifurcation lesion using commercially available stents, it is important to cover the origin of the branch because if left uncovered, this area is prone to restenosis. In order to cover the branch origin, conventional stents inserted into the branch must protrude into the lumen of the main artery or vessel from the branch (which may cause thrombosis, again compromising blood flow). Another frequent complication experienced when stenting bifurcated vessels is the narrowing or occlusion of the origin of a side branch spanned by a stent placed in the main branch. Additionally, placement of a stent into a main vessel where the stent partially or completely extends across the opening of a branch makes future access into such branch vessels difficult if

not impossible. As a result, conventional stents are often placed into the branch close to the origin, but generally not covering the origin of the bifurcation.

Lastly, conventional stents are difficult to visualize during and after deployment, and in general are not readily imaged by using low-cost and easy methods such as x-ray or ultrasound imaging. While some prior art balloon catheters (and not stents) are "marked" at the proximal and distal ends of the balloon with imageable patches, few stents are currently available which are marked with or which are at least partly constructed of, a material which is imageable by currently known imaging procedures commonly used when inserting the stents into a vessel, such as ultrasound or x-ray imaging. The invention described in this Application would not work with endoscopy as currently used as an imaging method due to size limitations, but future advances in limiting the size of endoscopic imaging devices may in the future make endoscopic imaging compatible with the stents of the invention.

Accordingly, there is a need for improved stent apparatuses, most particularly for applications within the cardiac, coronary, renal, peripheral vascular, gastrointestinal, pulmonary, urinary and neurovascular systems and the brain which 1) completely covers the bifurcation point of bifurcation vessels; 2) may be used to treat lesions in one branch of a bifurcation while preserving access to the other branch for future treatment; 3) allows for differential sizing of the stents in a bifurcated stent apparatus even after the main stent is implanted; 4) may be delivered intraluminally by catheter; 5) may be used to treat bifurcation lesions in a bifurcated vessel where the branch vessel extends from the side of the main vessel; and 6) is marked with, or at least partly constructed of, material which is imageable by commonly used intraluminal catheterization visualization techniques including but not limited to ultrasound or x-ray.

SUMMARY OF THE INVENTION

The present invention concerns novel stent apparatuses for methods, and kits use in treating lesions at or near the bifurcation point in bifurcated vessels. More particularly, the invention concerns a stent apparatus with a main tubular stent body having at least one side opening which may further comprise an extendable or second stent inserted through the side opening and at least partly in registry with the wall of the side opening.

As used herein, the term "vessel" means any body lumen or tubular tissue within the cardiac, coronary, renal, peripheral vascular, gastrointestinal, pulmonary, urinary and neurovascular systems and the brain. Devices constructed in accordance with the invention include, singularly or in combination, a main expandable tubular stent body having at least one side opening (usually substantially circular) located between its proximal and distal end openings, which side opening may further comprise a radially expandable portion extending laterally outward from the edges of the side opening; and an expandable branch second stent comprising proximal and distal end openings and which may further comprise a contacting portion at its proximal end, and which may be constructed to form an angularly variable branched stent apparatus when inserted through a side opening of the main stent. The radially expandable portion preferably comprises a plurality of laterally deployable elements, such as loops, tabs, beams, or the like, attached or coupled to a peripheral edge of the side opening. Usually, the elements will project inwardly from the periphery into the side hole so that they may be deployed radially outwardly from the periphery to open in a petal-like fashion. The elements may be formed integrally as part of the tubular body structure, e.g., being formed from the bent wire or band or from the cut tubular structure which defines the stent structure. Alternatively, they could be formed separately and subsequently attached by crimping, welding, folding, interference fitting, etc. Optionally, the expandable portion may be covered with a fabric or the entire stent structure membrane to help form the transition between the main body lumen and the lumen of the second stent. The stents of the invention are marked with, or at least partially constructed of, a material which is imageable during intraluminal catheterization techniques, most preferably but not limited to ultrasound and x-ray, preferably being radiopaque.

In a preferred aspect of the stent design, the side hole will be defined by a continuous band or pattern of material which defines the periphery of the side hole. The band may have a circular, oval, or other regular geometry in which case the width and area of the side hole will remain generally constant as the stent is expanded. Alternatively, the continuous band may comprise discontinuities over its length so that the area and/or width of the side hole may expand together with the stent structure. Preferably, the continuous band will include inwardly projecting loops, fingers, or other protrusions which will define the laterally deployable elements which project inwardly from the peripheral edge of the side opening. The inwardly projecting loops or other

elements may be overlapping or non-overlapping. The use of overlapping looped structures maximizes the length of the inwardly projecting elements after they are unfolded and opened inwardly into the side branch, as described in more detail below.

In another aspect of the present invention, a stent for placement in a bifurcated body lumen comprises a main tubular body having a first end, a second end, and a side opening therebetween. A first portion of the main tubular body between the first end and the side hole opens in response to a first radially outward pressure, typically provided by an expansion balloon. A second portion of the main tubular body between the side hole and the second end opens in response to a second pressure, again typically applied by an expansion balloon. By constructing the main tubular body so that the first opening pressure is less than the second opening pressure, the stent can have differential opening characteristics. That is, by introducing a balloon expansion catheter into the stent and applying a constant pressure over the entire length of the balloon, the first portion of the stent will yield and open before the second portion of the stent. The particular embodiments described below, the first yield pressure will typically be in the range from 1 atmospheres to 10 atmospheres while the second yield pressure will typically be in the range from 2 atmospheres to 18 atmospheres. Such stent structures may be placed by initially opening and deploying the first portion, typically the proximal portion on the same side of the bifurcation as the deployment catheter, and thereafter positioning the side hole to align more precisely with the bifurcated secondary blood vessel. After the proper positioning has been achieved, the second stent portion can then be opened, conveniently using the same expansion balloon which has been inflated to a higher inflation pressure. Such stents will typically include the laterally deployable elements disposed around the side opening, as described above, and will optionally be used in combination with secondary stents, as described above.

The stent structures as described previously may combine conventional stent elements, such as serpentine rings, diamond or box structures, axial expansion members, and the like. In addition, in order to provide the differential expansion characteristics, the main tubular bodies of the stents may include axial spine structures which differ from the remaining portions of the tubular body of the stent. For example, the first portion of the stent may have an axial spine which readily expands circumferentially. By then providing a spine section on the second portion of the stent which is more resistant to circumferential expansion, the desired differential expansion

will be achieved. Alternatively, the differential expansion can be achieved by employing stent patterns which are uniformly easier or more difficult to radially expand over their entire peripheral length. Specific examples of both structures will be described below.

The stent apparatuses of the invention offers significant and novel advantages over prior art stents in that the stents of the invention 1) can completely cover the bifurcation point of a branched vessel; 2) can accommodate main and branch stents of differing sizes, thus providing a better fit where the main and branch vessels are of different sizes or where the main and branch vessels are occluded to different degrees; 3) can fit branched vessels where the branch extends laterally from the side of the main vessel; 4) may be used to treat lesions in one branch of a bifurcation while preserving complete access to the other branch for future treatment; 5) may be delivered intraluminally by catheter; and 6) are marked with, or at least partly constructed of, material which is imageable by commonly used intraluminal catheterization visualization techniques including but not limited to ultrasound or x-ray, but not endoscopy.

Thus, it is an object of the present invention to provide both a double-stent apparatus and a single-stent apparatus, each of which may be used to cover the origin of a bifurcation in a branched vessel.

Another object of the invention is to provide a single-stent apparatus which may be used to treat only one branch of a bifurcation lesion while leaving access to the second branch unobstructed.

Additionally, it is an object of the invention to provide a stent apparatus which is itself imageable by methods commonly used during catheterization such as x-ray or ultrasound.

Yet another object of the invention is to provide a bifurcating double-stent device wherein the main stent and the branch stent or stents may be of different sizes.

Lastly, it is an important object of the invention to provide a stent apparatus which may be used to treat bifurcated vessels where the vessel bifurcation extends laterally from the side of the main vessel.

These objects and other object advantages and features of the invention will become better understood from the detailed description of the invention and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic depiction of the double-stent apparatus of the present invention in which both the main stent and the branch stent are fully dilated.

Fig. 2 is a schematic depiction of the main stent of the apparatus of the invention as deployed, with the side opening in registry with a vessel bifurcation point.

Fig. 3 is a schematic depiction of the branch stent of the apparatus as deployed, with the contacting portion fully expanded to contact the origin of the bifurcated vessel.

Fig. 4 is a schematic depiction of the main stent of the apparatus deployed within a subject vessel, after inflation of a balloon to expand the main stent to fit the walls of the subject vessel.

Fig. 5 is a schematic depiction of the double-stent bifurcating stent apparatus, where the main stent is deployed and showing the placement of the branch stent apparatus prior to full deployment of the branch stent.

Fig. 6a depicts initial placement of the main stent of the bifurcating stent apparatus into the vessel, along with the insertion of a guidewire and stabilizing catheter for placement of the branch stent into the branch vessel of the subject.

Fig. 6b is a schematic depiction showing the main stent of the invention expanded by balloon expansion.

Fig. 6c is a schematic depiction of the deployment of the branch stent over the side branch guidewire, through one of the side openings in the main stent and into the branch vessel of the subject.

Fig. 6d is a schematic depiction of the removal of the protective sheath of the branch stent allowing for full expansion of the contacting portion prior to final placement and deployment.

Fig. 6e is a schematic depiction of the compressed branch stent positioned into the branch by the catheter with the contacting portion at least partly contacting the side opening in the main stent, but prior to full expansion of the branch stent.

Fig. 6f is a schematic depiction of the fully expanded main stent and the fully positioned and expanded branch stent, where the branch stent is being dilated by inflation of a balloon.

Fig. 6g is a schematic depiction of the fully expanded bifurcating double stent of the invention, positioned into the bifurcation point in a subject vessel.

Fig. 7 is a schematic depiction of the main stent with optional expandable portion, prior to balloon expansion of the expandable portion.

Fig. 8 is a schematic depiction of balloon expansion of the optional expandable portion of the main stent to cover a vessel bifurcation point.

Fig. 9 is a schematic depiction of the main stent with the optional expandable portion fully expanded to extend laterally from the side opening of the main stent.

Fig. 10 illustrates a first stent pattern having a side hole and differential expansion characteristics in a "rolled out" view.

Fig. 11 illustrates a second stent pattern having a side hole and differential expansion characteristics in a "rolled out" view.

Fig. 12 illustrates a third stent pattern having a side hole and differential expansion characteristics in a "rolled out" view.

Figs. 13A-13H illustrate the deployment of any one of the stents of Figs. 10-12 in a bifurcated blood vessel or a secondary stent is placed through the side hole of the main stent.

The rectilinear matrices shown in the drawings are intended to show the shapes of the surfaces only, and do not illustrate the actual surface patterns or appearances of the stent apparatuses of the invention.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The bifurcating double-stent apparatus 10 of the present invention comprises a generally cylindrical main stent 12 and a generally cylindrical branch stent 15, which are shown as fully dilated in a subject main vessel 8 and a subject branch vessel 7, as illustrated in Fig. 1.

The main stent 12 contains at least one generally circular side opening 16 located between the proximal end 26 and the distal end 28 of the main stent 12 (Fig. 2), which opening is positioned over and in registry with the opening 48 of a branch vessel in a vessel bifurcation 50, as shown in Fig. 2. The stent 12 and the side opening are imaged during imaging procedures either by constructing the stent of imageable materials or by placing markers 56 at appropriate locations, such as around the perimeter of the side opening 16 in the main stent 12, and at the proximal end 26 and distal end 28 of the main stent, as illustrated in Fig. 4.

As shown in the embodiment of the invention illustrated in Fig. 4, a guidewire 20 is inserted into the vessel 8 prior to insertion of the main stent 12, and is used to guide the main stent 12 into position within the vessel 8. Prior to insertion and expansion, the main stent 12 is disposed around the distal end of a catheter 48 which may include an inflatable balloon 24. The main stent/catheter apparatus is then threaded onto the main guidewire 20 and into the vessel 8. The main stent 12 is radially expanded by inflation of the balloon 24 until it expands the walls of the vessel 8, and is thus affixed into place.

In a second embodiment of the invention, the branch stent apparatus 15 of the present invention comprises a generally cylindrical stent comprising a proximal end 30 and a distal end 32, as shown in Fig. 3. The proximal end 30 comprises a contacting portion. illustrated here as extended loops 18, which contacting portion, when expanded, is positioned within the lumen 58 of the main vessel 8 (Fig. 3) and at least partially contacting the perimeter of the side opening 16 of the main stent 12. Fig. 4 illustrates the positioning of the main stent 12 (without optional contacting portion) in the main vessel 8 as fully expanded by inflation of the balloon 24.

As shown in the embodiments illustrated in Figs. 4, 5 and 7, the ends of the main stent 12 and the expandable branch stent 15 and the contacting portion 18 are visible during insertion by placing imageable markers 56 around the ends of the main 12 and branch 15 stents and the contacting portion 18 and at the proximal end 30 and distal end 32 of the branch stent. Alternatively, the stent may be at least partially constructed of material which is imageable by methods including but not limited to ultrasound or x-ray imaging (but not endoscopic imaging).

As shown in yet another embodiment, the stents of the invention are combined to form a bifurcating double stent as illustrated in Figs. 5 and 6a-g. After insertion of the main stent as described above but prior to expansion of the main stent (Fig. 6a), the branch stent 15 is inserted through a side opening 16 of the main stent 12, a guidewire 36 and a stabilizing catheter 44 are inserted through the side opening 16 in the main stent 12, and into a branch vessel 7 (Fig. 6a). The stabilizing catheter 44 is used to place the side opening 16 in the main stent 12 over the bifurcation point 50 in the bifurcated vessels 7 and 8 (Fig. 6a). In the embodiment depicted here, the main stent is then deployed into position by inflation of the balloon 24 (Fig. 6b). During insertion and prior to dilation of the branch stent, the branch stent 15 is disposed around the distal end

of a branch catheter 54 which may optionally include an inflatable balloon 25, and the contacting portion 18 of the branch stent 15 is held in a collapsed position by a protective sheath 34, as shown in Fig. 6c.

In the bifurcating double-stent apparatus 10 of the invention, once the main stent 12 is dilated and the stabilizing catheter 44 (as shown in Fig. 6b) is removed, the branch stent 15 is inserted over the branch guidewire 36 and through the opening 16 of the main stent 12 substantially as shown in Fig. 6c, and affixed in place by withdrawal of the protective sheath 34 (Fig. 6d) and insertion of the branch stent 15 until it at least partially contacts the perimeter of the opening 16 of the main stent 12 by the expansion of the contacting portions 18 which are positioned at the proximal end 30 of the expandable stent, as shown in Fig. 6e. The branch stent 15, once positioned in the branch vessel 7, may be then fully expanded by the balloon 25, as shown in Fig. 6f. The angle at which the optionally expandable branch stent 15 is affixed depends upon the vessel structure into which the bifurcating stent apparatus 10 is inserted. All catheters and guidewires are then withdrawn from the subject vessels, leaving the main stent 12 through which the branch stent 15 is inserted into the branch vessel 7, forming a bifurcated stent 10 (Fig. 6g).

As illustrated in Figs. 6a-6g, the main stent 12 is deployed prior to the branch stent 15. This is the presently preferred order of deployment. It will be possible, however, in some circumstances to deliver the branch stent 15 prior to the main stent 12. In such cases, the branch stent 15 will be deployed with the contacting portions 18 opened directly against the inner wall of the main blood vessel. The main stent 12 will then be positioned over the contacting portions 18 of the branch stent 15 and firmly expanded thereagainst. A sheath or expansion balloon can be used to properly align the side opening 16 of the main stent 12 with the opening within the contacting portion 18 of the branch stent 15.

In the embodiment shown in Figs. 7-9, the main stent 40 with expandable portion 38 is positioned within the vessel 8 by the guidewires 20 (Fig. 7), and affixed in place by radial expansion of the main stent 40, most particularly by inflation of the balloon 25 (Fig. 8). The main stent is positioned so that the opening 16 is directly over the bifurcation point 50 in the subject vessels 7 and 8 (Fig. 7 and 8). In order to aid such positioning, a side branch guidewire 36 and a stabilizing catheter 44 (as depicted in

Fig. 7) are also inserted through the opening 16 of the main stent 40 and through the expandable portion 38 and into the branch vessel 7 (Fig. 8).

The optional expandable portion 38 of the main stent 40 is then expanded radially and in an at least partially perpendicular manner to the sides of the main stent side opening 16 (Fig. 8). In the embodiment illustrated in Figs. 7 and 8, a balloon 25 is deployed along the side branch guidewire 36 through the expandable portion 38, and inflated until the expandable portion is fully expanded into the branch vessel 7 to cover the bifurcation point 50 of the branched vessel, as illustrated in Fig. 8. In order to extend the expandable portion 38 into the branch vessel 7, a balloon 25 disposed around a branch catheter 54 which is threaded along the side branch guidewire 36, through the main stent 40, through the opening 16 and expandable portion 38, and into the subject branch vessel 7 as shown in Fig. 8. The expandable portion 38 is then extended into the branch vessel 7 by inflation of the balloon 25, which pushes the expandable portion 38 outward radially and lateral to the side opening, into the branch vessel 7 (Fig. 8). Once all catheters and balloons are withdrawn, the expandable portion 38 is arrayed in lateral orientation to the sides of the opening 16 in the main stent 40, and surrounding the opening 16 into the vessel branch (Fig. 9). The guidewires 20 and 36 are then withdrawn from the main and branch vessels.

The expandable portion 38 is illustrated as a plurality of elements which are attached to the peripheral edge of the side opening 16. The elements project radially inwardly into the side opening and thus lie within the cylindrical envelope of the tubular main stent 40 prior to deployment, as shown in Fig. 7. The elements are opened by outward lateral deflection, typically using a balloon catheter, as illustrated in Fig. 8. The deflected elements both traverse the transition between the stent and the lumen of the branch vessel and also serve as an anchor for subsequent placement of the second stent.

In the double stent apparatus of Fig. 5 and in the main stent with expandable portion illustrated in Figs. 7 and 9, the main stent as well as the expandable portions may be constructed at least partially of and/or coated or plated with an imageable material or marked with imageable markers 56 at suitable locations, including around the perimeter of the side openings of the main stent and at the ends of the expandable portions. In the differentially expandable stent structures of Figs. 10-12 (described below), a distal portion may be radiopaque with the remainder being radiolucent. Suitable imageable materials are radiopaque, such as gold, tungsten, and the like.

When reinforcing a bifurcated vessel where both branches of the vessel require reinforcing, either 1) the single main stent with the expandable portion is used whereby the expandable portion extends into the vessel branch at least partly covering the origin of the bifurcation, which may be used alone or in combination with any conventional stent; or 2) the main stent without the expandable portion and at least one branch stent with contacting portion are used, the branch stent placed to extend through at least one side opening of the main stent into at least one branch vessel, wherein the branch stent is at least partially in registry and contacting the edge of the side opening through which it extends. The branch stent extends laterally at varying angles to the side opening of the main stent. When treating a bifurcated vessel where the area to he treated spans the bifurcation and unobstructed access to the unstented vessel is required, the main stent may be used either with or without the expandable portion, wherein at least one side opening is placed over the bifurcation point.

The stent apparatus of the invention may be constructed from any non-immunoreactive material, including but not limited to any of the materials disclosed in the prior art stents which are incorporated herein by reference. It is intended that the stent apparatuses of the invention may further be at least partially constructed of, or marked at certain points with, a material which may be imaged, most particularly but not limited to by x-ray and ultrasound.

The stents of the invention may be deployed according to known methods utilizing guidewires and catheters, which are then withdrawn from the subject following deployment of the stents. The subject stents may be self-expanding to conform to the shape of the vessel in which they are deployed, or they may be expanded utilizing balloon catheters, or by any other method currently known or developed in the future which is effective for expanding the stents of the invention. It is contemplated that prior to deployment the stents will be in a collapsed state, and will require either mechanical expansion (such as, for example, by balloon expansion) upon deployment or, for self-expanding stents, will require that the stent be confined to the catheter until deployment by, for instance, a retractable sheath, in which the sheath is removed during deployment and the stent self-dilated. The stents of the invention and the optional expandable portion of the main stent of the invention expand radially from their longitudinal axis, lateral to the side opening of the main stent. Other methods of dilation of the stents of the

invention may exist, or may become available in the future, and such methods are contemplated as being within the scope of this invention.

Referring now to Figs. 10-12, the present invention further provides stent structures having differential radial expansion characteristics. In particular, tubular stent structures having side holes, generally as described above, are configured so that a portion of the stent on one side of the side hole will expand at a different yield or threshold force than a portion of the stent on the other side of the side hole. Such different yield forces or pressures may be achieved in a variety of ways. For example, referring to Fig. 10, a stent 100 is illustrated in a "rolled out" view, i.e., the tubular stent is broken along an axial line and then rolled out in the resulting pattern shown in the Figure. The pattern shown in Fig. 10 is prior to expansion. The stent 100 includes a side hole 102 defined by a continuous band 104 having a plurality of loops 106 projecting into the open interior of the side hole. The loops 106 are an integral part of the band 104 and will, prior to expansion or opening, lie within the cylindrical envelope of the tubular body of the stent. The first portion 110 of the stent lies on one side of the side hole 102 and is defined by a plurality of serpentine rings 112. The serpentine rings are joined by axial expansion spring structures 114 so that the stent may be bent as it is introduced and/or deployed. A second portion 120 of the stent 100 is formed on the other side of side hole 102. The second portion is also defined by the plurality of serpentine rings 122 which are generally similar in structure to the rings 112 of the first portion 110. Each of the portions 110 and 120, however, include an axial spine 130 and 132. The axial spine 130 of the first portion 110 comprises simple W-shaped structures including outermost struts 134 which open at a relatively low expansion force on the adjoining hinge regions. In contrast, the axial spine 132 of the second portion 120 comprises box elements 138 which require a greater expansion force to open. Thus, in deployment, the first portion 110 will yield first to allow partial opening before the second portion 120 begins to open.

A second stent structure 200 having differential expansion characteristics is illustrated in Fig. 11. A side hole 202 is formed from a continuous band of material, generally as described for Fig. 10. A first portion 204 and second portion 206 of the stent each comprise a plurality of serpentine ring structures 208 and 210, respectively. While the specific geometries differ, the structures of stents 100 and 200 are generally the same, except for axial spine portions 220 and 230 in the first portion 204 and second portion 206, respectively. The first spine portion 220 comprises a simple U-shaped loop

having a pair of struts joined by a simple C-shaped hinge region. The spine 220 will thus open at relatively low expansion forces. In contrast, the axial spine 230 of the second portion 206 comprises a serpentine element which allows for axial expansion but does not permit radial expansion at all. Thus, the first portion 204 will begin opening at much lower expansion forces or pressures than will the second portion 206.

A third concept for providing differential expansion is illustrated in Fig. 12. Stent 300 comprises a side hole 302 (which is shown in halves in the illustration), a first portion 304, and a second portion 306. The first portion 304 and second portion 306 each comprise serpentine rings 308 and 310, respectively. Differential expansion, however, is not achieved by providing a particular axial spine region, but rather by having different characteristics in the serpentine rings 308 and 310. The serpentine rings 308 have axially aligned struts joined by simple hinge regions. The length of the struts is relatively long (compared to those in the second portion 306 as described below) so that the rings will open at a lower expansion pressure or force. The serpentine rings 310 of the second portion 306 have relatively short axial struts defined by hinge regions each having two bands. Such structures require a greater expansion force than do the serpentine rings 308 of the first portion.

It will be appreciated that numerous other specific designs may be provided for differential expansion. What is important to the present invention, however, is that at least a portion of the stent on one side of the side hole, usually the entire length of the stent on that side of the hole, will be able to open prior to opening of the stent on the other side of the side hole. Preferably, the first portion of the stent will open at a balloon expansion pressure in the range from 1 atmospheres to 10 atmospheres, while the second portion of the stent will open in response to a balloon expansion pressure in the range from 2 atmospheres to 18 atmospheres.

Referring now to Figs. 13A-13H, deployment of stent 100 will be described. While reference is made to stent 100, it will appreciated that the same method could be used as well with either of stents 200 or 300. Initially, a pair of guidewires GW1 and GW2 will be deployed in the lumen, typically a bifurcated blood vessel, so that guidewire GW1 extends through the main lumen of the main vessel past the ostium O of the branch vessel BRV. The second guidewire GW2 will be advanced through the lumen of the main vessel and into the lumen of the branch vessel BRV, as illustrated in Fig. 13A. The stent 100 will then be introduced over the guidewires on a delivery

catheter 400 having an expansion balloon 402, where the stent is crimped over the expansion balloon. A sheath 404 is disposed in the second portion 120 of the stent with its distal tip (not shown) terminating immediately before the side opening 102. The assembly of the stent 100, delivery catheter 400, and sheath 404 will be delivered with the first guidewire GW1 passing through a guidewire lumen of catheter 400 and the second guidewire GW2 passing through the sheath 404, as illustrated in Fig. 13B. Initial alignment of the side hole 102 of stent 100 is achieved by advancing the stent so that the side hole lies close to the ostium O.

After an initial rough alignment is achieved, the balloon 402 is inflated to an initial inflation pressure which opens the first portion 110 but which leaves the second portion 120 in its substantially unexpanded configuration, as shown in Fig. 13C. Such partial opening allows the sheath 404 to be advanced over guidewire GW2 to better align the side hole with the branch vessel BRV, as shown in Fig. 13D. The sheath provides much greater stiffness than the guidewire, permitting manipulation of the partially deployed stent 100 to achieve the better alignment.

Referring now to Fig. 13E, after alignment is achieved, the balloon 402 will be inflated to a greater inflation pressure to open the second portion 120 of the stent 100 as well. A balloon catheter can then be advanced over the second guidewire GW2 so that balloon 502 can be expanded within the side opening 102 to open the loops 106, as illustrated in Fig. 13F. In many cases, this will be sufficient deployment for the stent where the loops provide the necessary anchoring and transition at the ostium O.

Optionally, a secondary stent 600 may be introduced as illustrated in Figs. 13G and 13H. The stent 600 is introduced over a balloon 702 on balloon catheter 700. The final deployment configuration is illustrated in Fig. 13H.

It is intended that the invention include all modifications and alterations from the disclosed embodiments that fall within the scope of the claims of the invention.

WHAT IS CLAIMED IS:

1. A stent for placement in a bifurcated body lumen having a main branch and a side branch, said stent comprising:

a main tubular stent body having a first end, a second end, a lumen therethrough, and a side opening have a plurality of laterally deployable elements therein.

2. A stent as in claim 1, wherein the elements are formed as an integral part of the stent body.

3. A stent as in claim 2, wherein, prior to deployment, the laterally deployable elements are aligned in a tubular envelope defined by the tubular stent body.

4. A stent as in any of the preceding claims, wherein the main tubular stent body is resilient so that it may be released from constraint for deployment.

5. A stent as in any of the preceding claims, wherein the main tubular stent body is deformable so that it may be expanded by a balloon catheter.

6. A stent as in any of the preceding claims, wherein at least a portion of the main stent body is radiopaque.

7. A stent as in claim 6, wherein at least a portion of the main stent body surrounding the side hole is radiopaque.

8. A stent as in any of the preceding claims, having a radially compressed configuration, wherein the length is less than 4 cm and the diameter is less than 2 cm.

9. A stent as in any of the preceding claims, wherein the side hole comprises a continuous band.

10. A stent as in claim 9, wherein the laterally deployable elements are inwardly projecting loops of the continuous band.

11. A stent for placement in a bifurcated body lumen, said stent comprising:

a main tubular body having a first end, a second end, and a side opening between said ends, wherein a first portion of the main tubular body between the first end and the side hole opens in response to a first radially outward pressure and a second portion of the main tubular body between the side hole and the second end opens in response to a second pressure, wherein the first pressure is less than the second pressure.

12. A stent as in claim 11, wherein the first pressure is in the range from 1 atmospheres to 10 atmospheres and the second pressure is in the range from 2 atmospheres to 18 atmospheres.

13. A stent as in claim 11 or 12, wherein the first portion has a first axial spine and the second portion has a second axial spine, wherein the first axial spine opens circumferentially to a first force and the second axial spine opens circumferentially in response to a second force, wherein the first force is less than the second force.

14. A stent as in claim 11 or 12, wherein the first portion comprises serpentine rings with a first strut length and the second portion comprises serpentine rings with a second strut length, wherein the first strut length is greater than the second strut length.

15. A stent system comprising:

(a) a stent as in any of the preceding claims; and

(b) a second stent adapted to fit within and contact the laterally deployable elements of the main tubular stent.

16. A method for attaching a second stent to a first stent, said method comprising:

expanding a main tubular stent body; and

laterally deflecting a plurality of elements disposed about a side opening on the main tubular stent body.

17. A method as in claim 16, further comprising placing a second stent into the side hole so that said second stent engages the laterally deflected element.

18. A method for deploying a stent in a bifurcated body lumen, said method comprising:

providing a stent having a first portion, a second portion, and a side hole between said portions;

expanding a first portion against a luminal wall segment on one side of the bifurcation;

aligning the side hole with the branch lumen; and

expanding the second portion on the other side of the bifurcation.

19. A kit comprising:

a stent as in any of claims 1 to 10; and

instructions for use setting forth a method including the following steps:

(a) expanding the main tubular stent body in a body lumen so that a side hole on the stent body is aligned with a branching body lumen; and

(b) laterally deflecting a plurality of elements disposed about the side opening so that they enter into the branching body lumen.

20. A kit comprising:

a stent system in claim 9; and

instructions for use setting forth a method including the following steps:

(a) expanding the main tubular stent body in a body lumen so that a side hole on the stent body is aligned with a branching body lumen;

(b) laterally deflecting a plurality of elements disposed about the side opening so that they enter into the branching body lumen; and

(c) placing the second stent into the side hole so that said second stent engages the laterally deflected plurality of elements.

21. A kit comprising:

a stent as in any of claims 11-14; and

instructions for use setting forth a method comprising the following steps:

(a) expanding a first portion against a luminal wall segment on one side of the bifurcation;

(b) aligning the side hole with the branch lumen; and

(c) expanding the second portion on the other side of the bifurcation.

Fig. 1

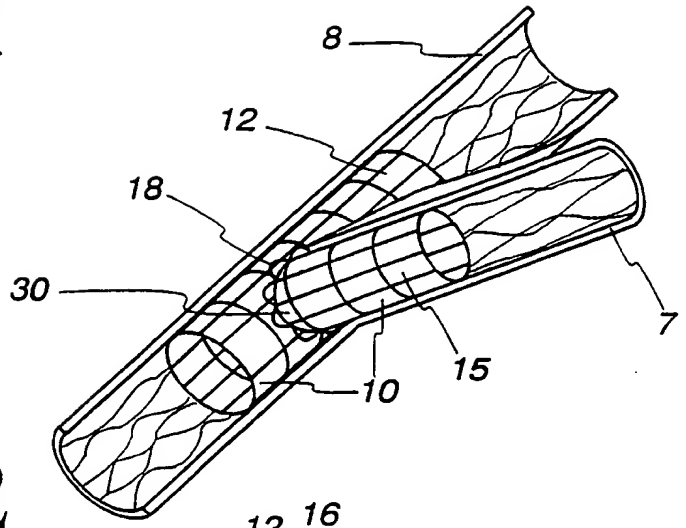


Fig. 2

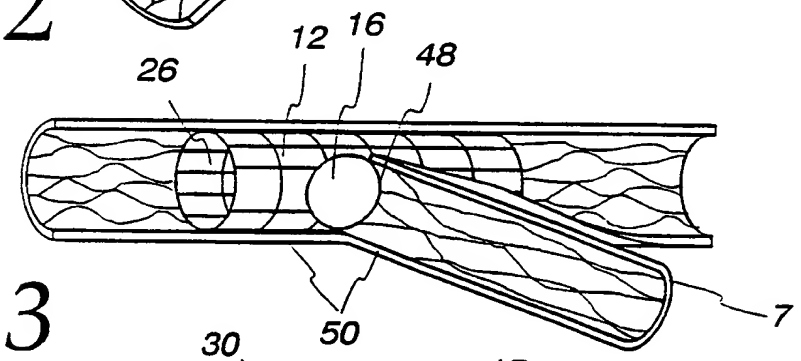


Fig. 3

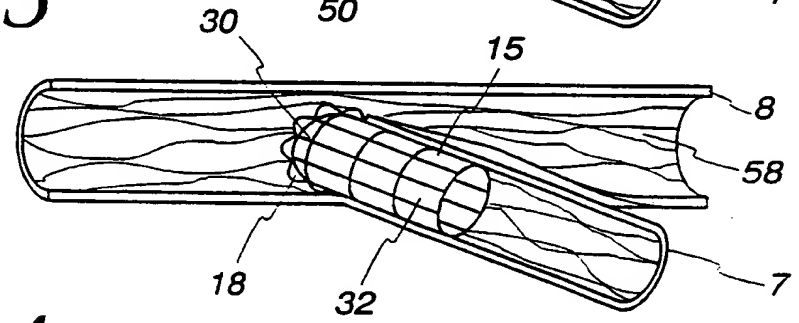
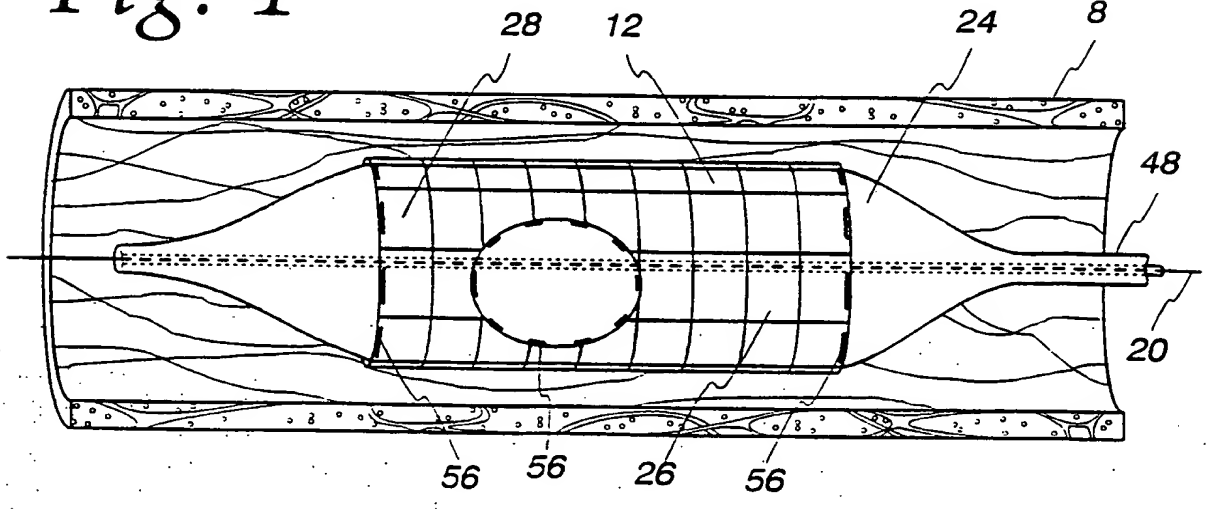


Fig. 4



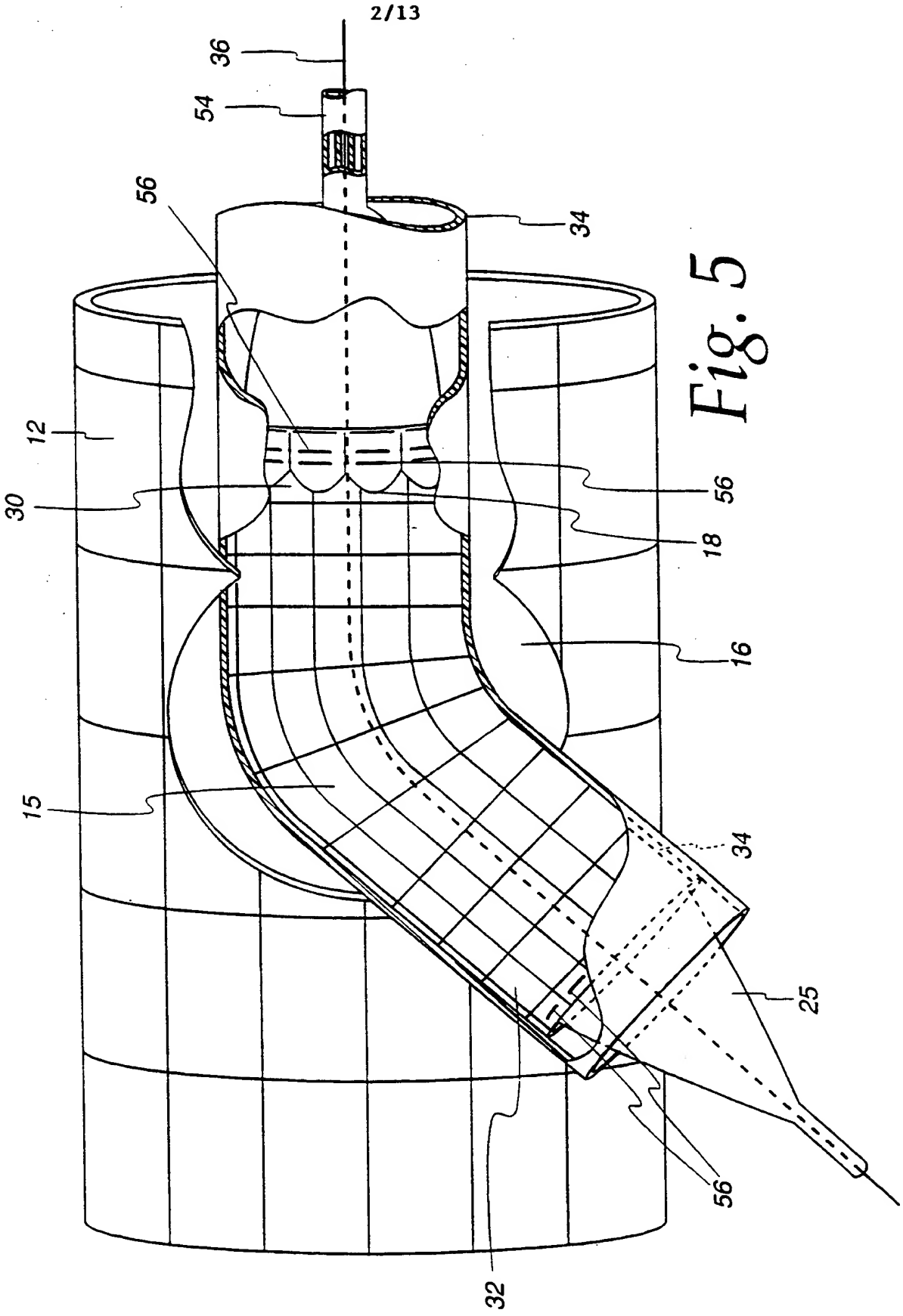


Fig. 5

Fig. 6a

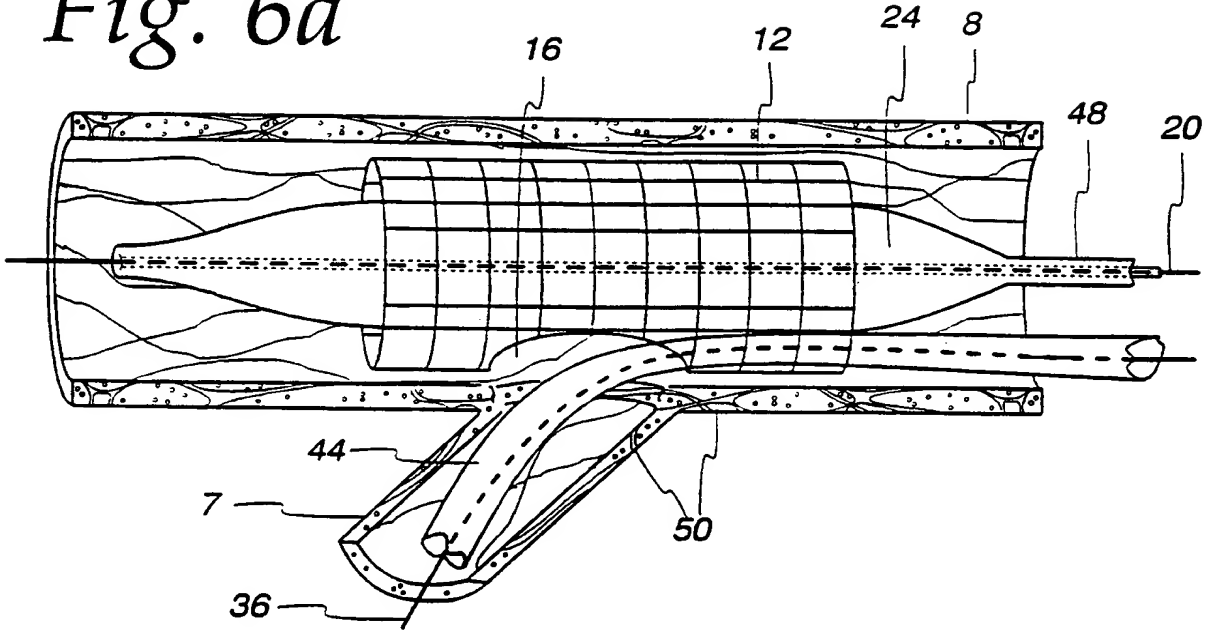


Fig. 6b

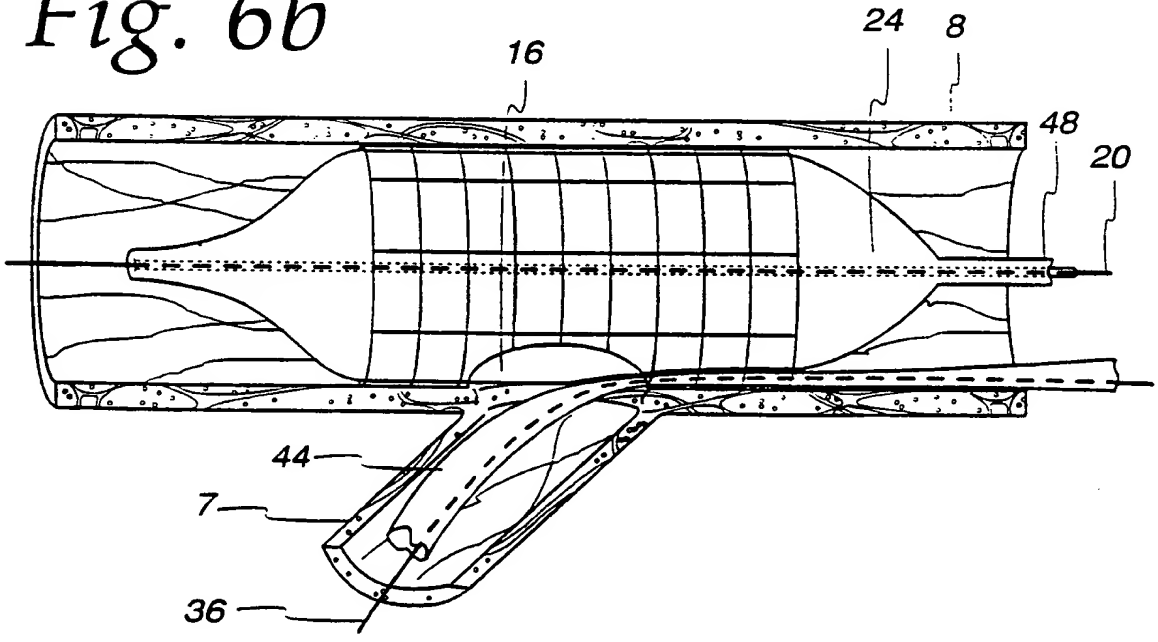


Fig. 6c

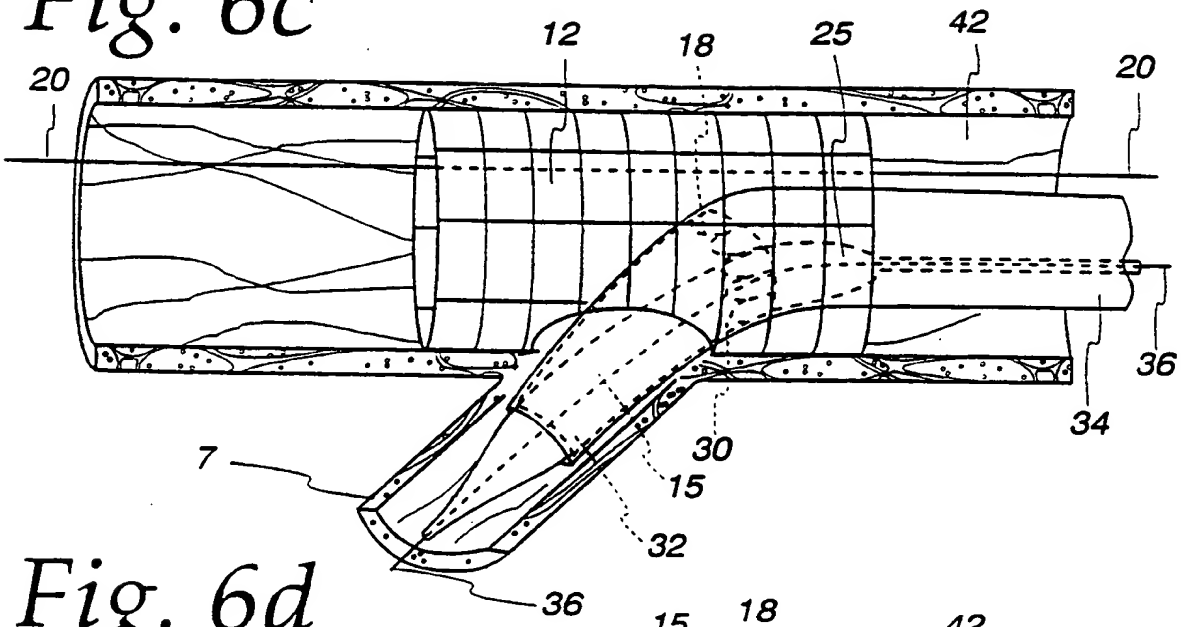


Fig. 6d

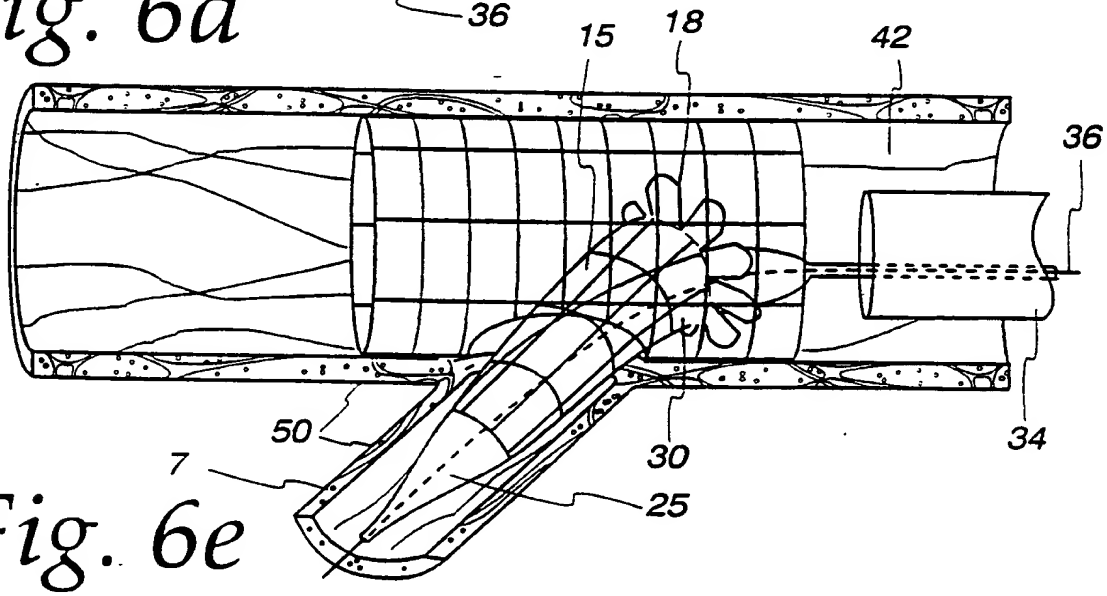


Fig. 6e

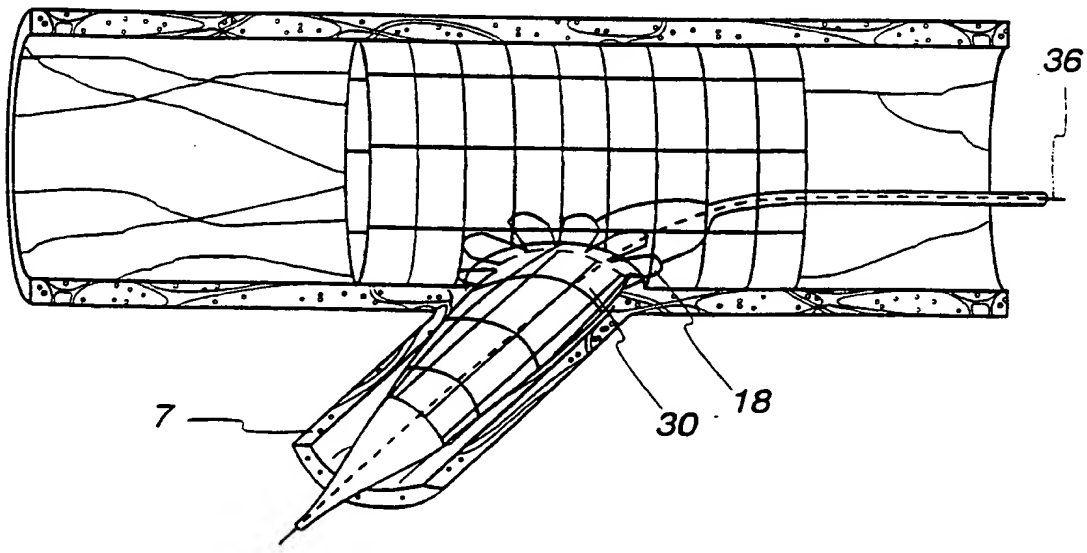


Fig. 6f

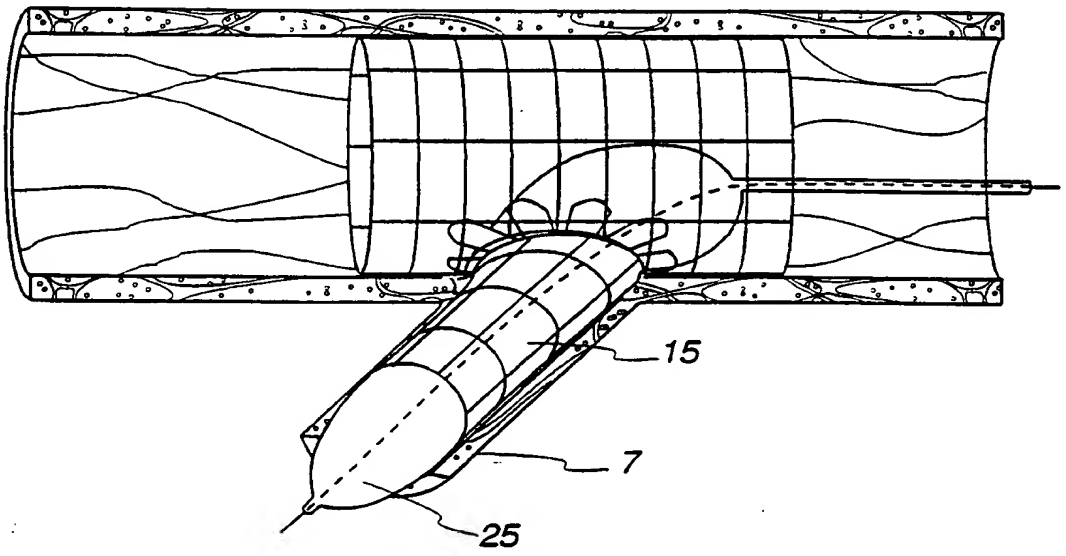


Fig. 6g

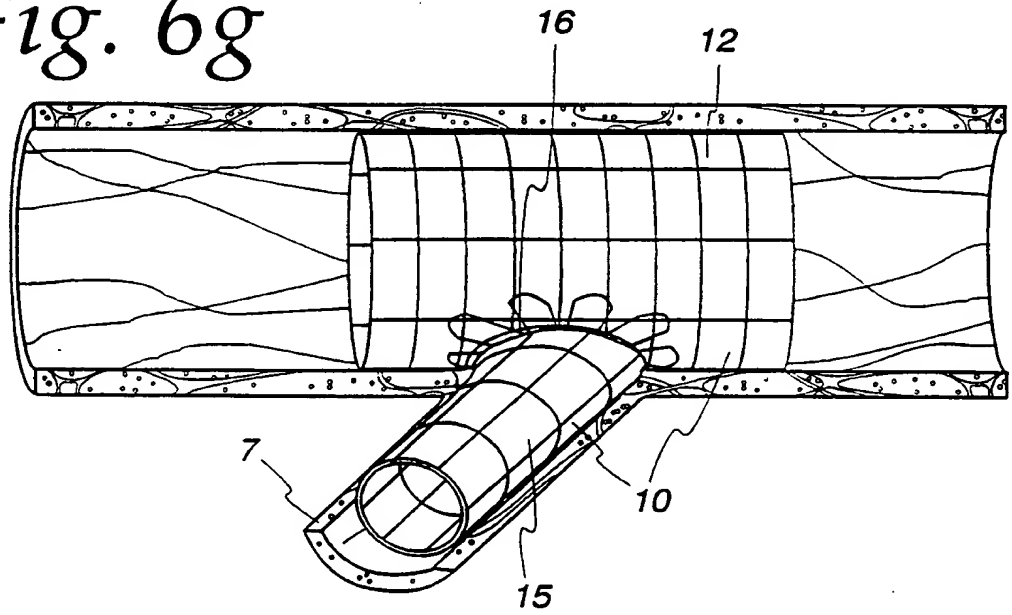


Fig. 7

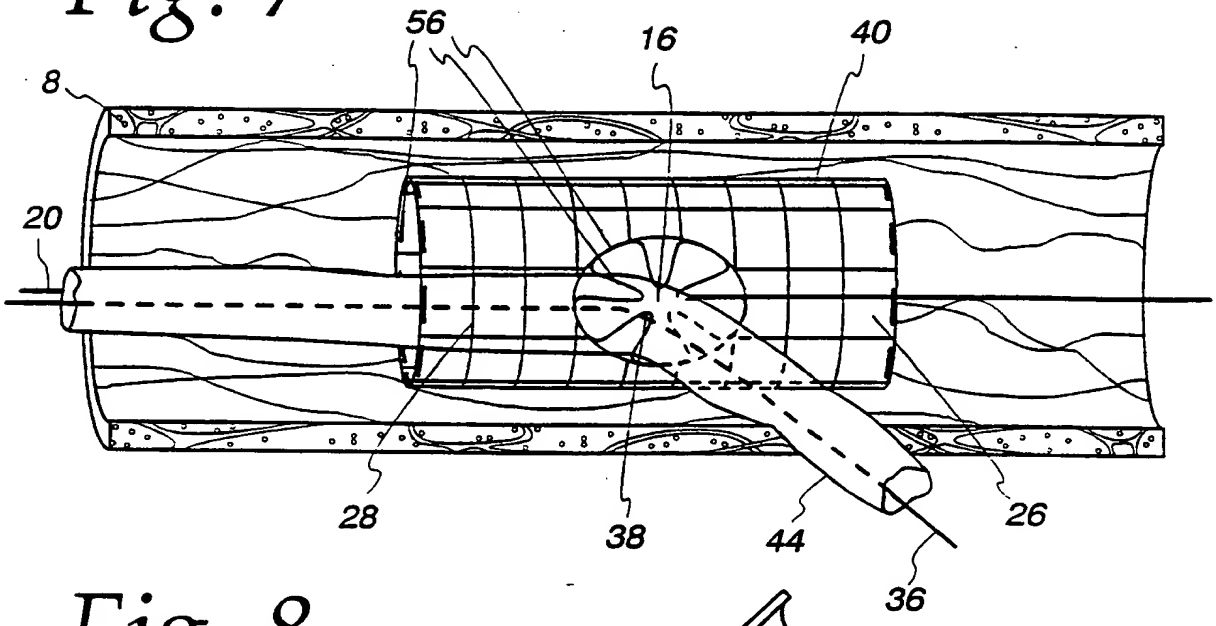


Fig. 8

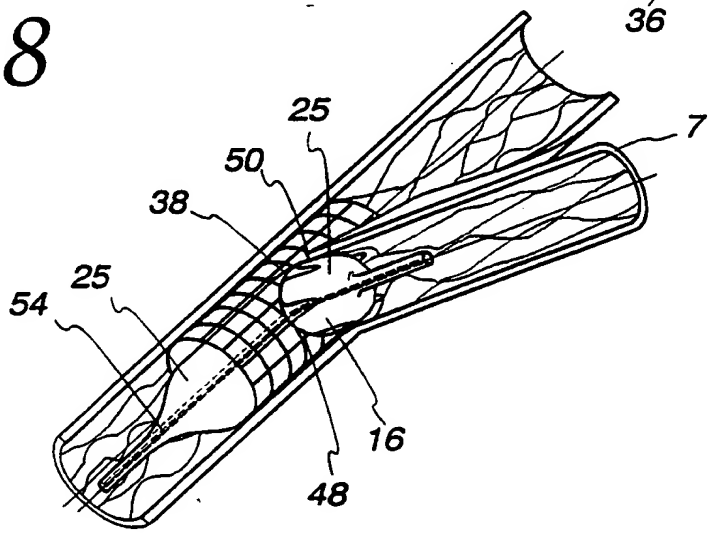
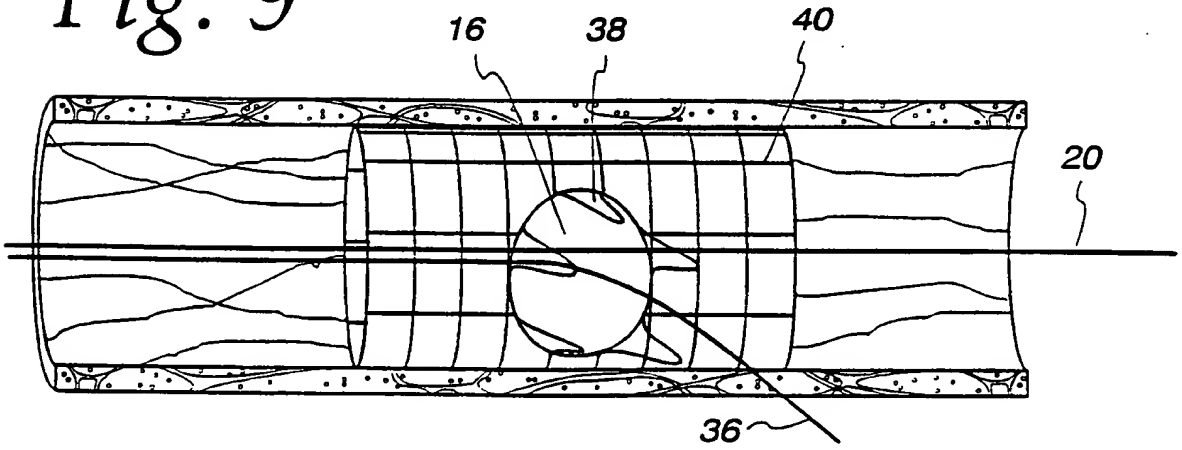


Fig. 9



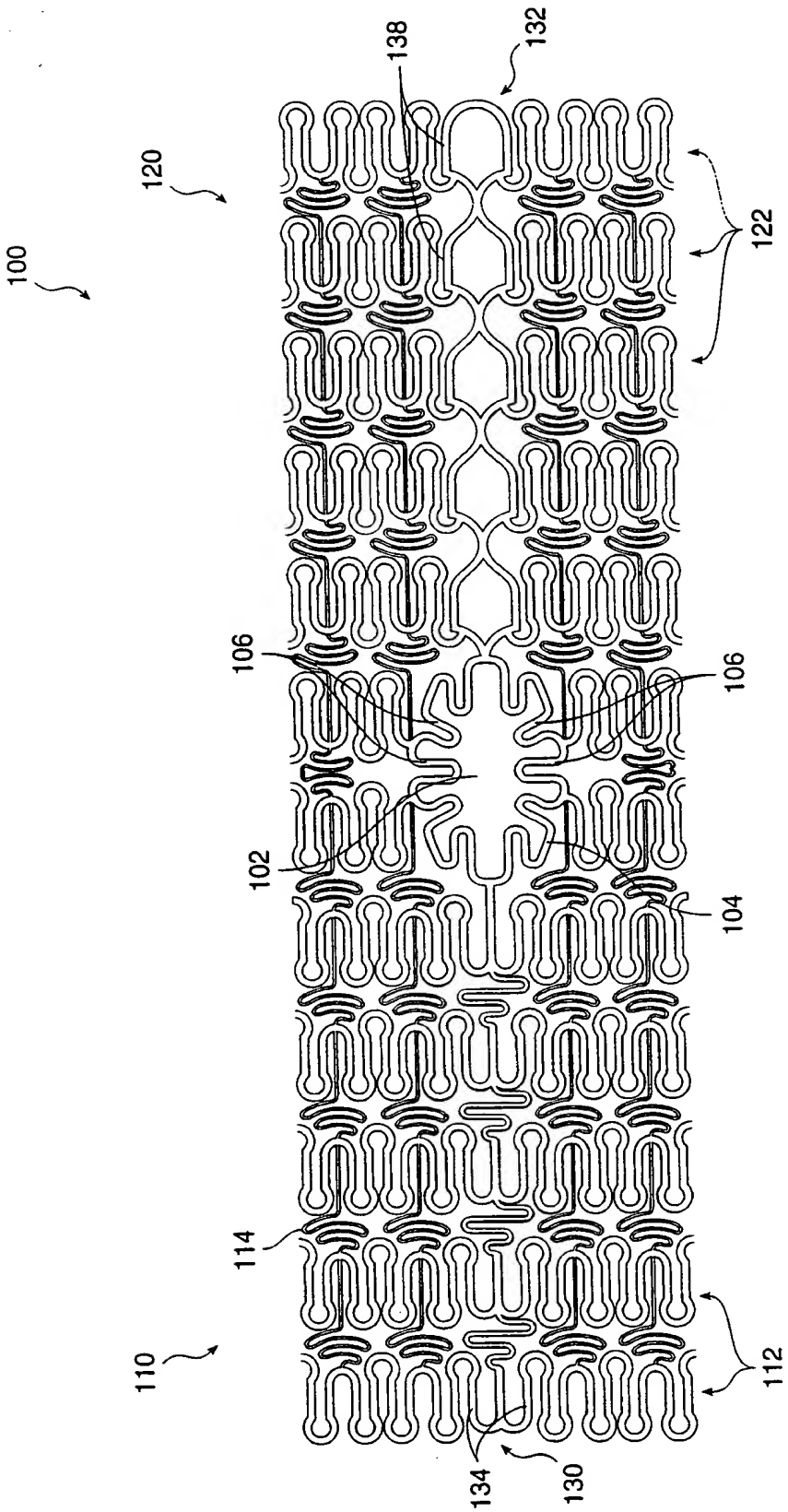


FIG. 10

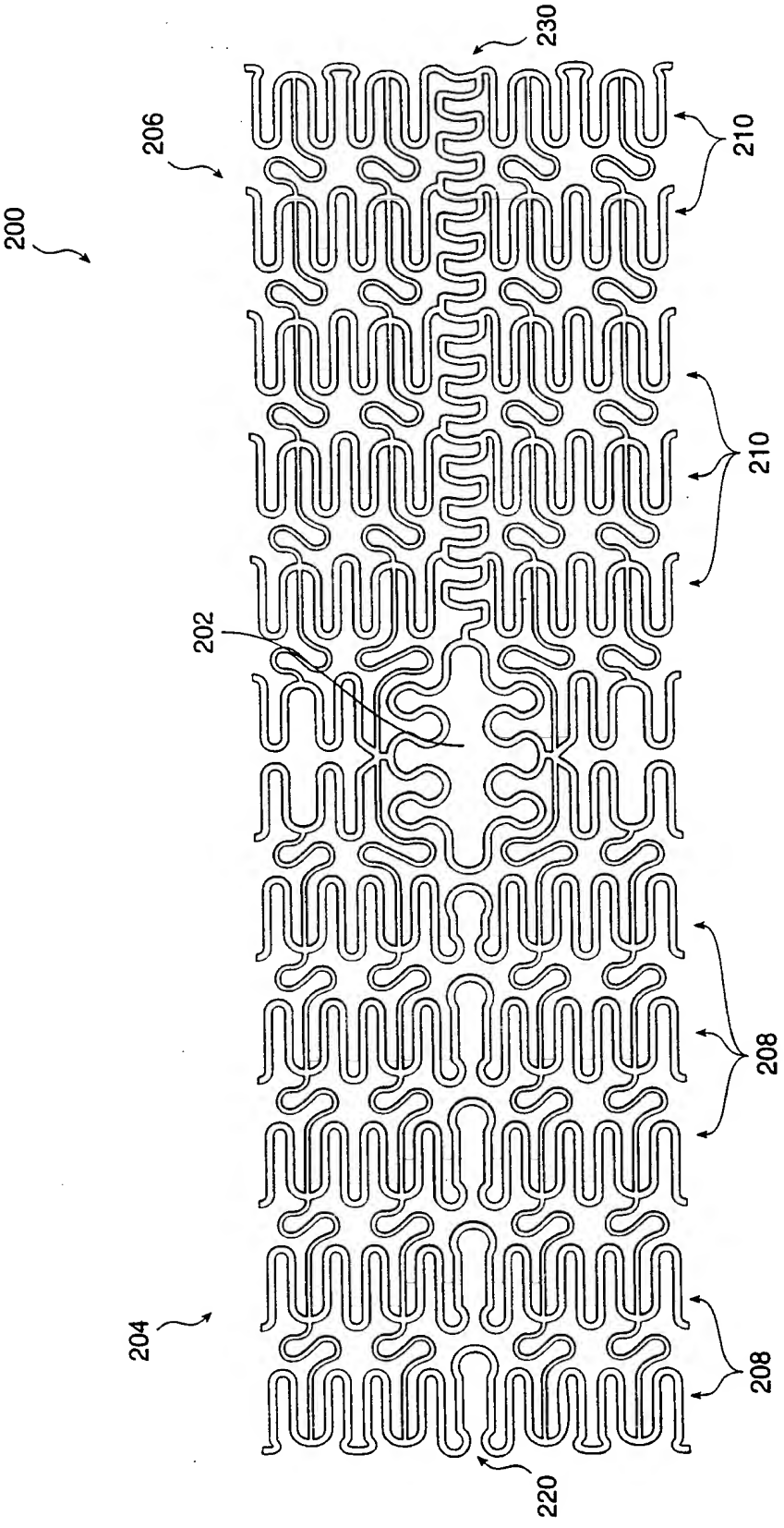


FIG. 11

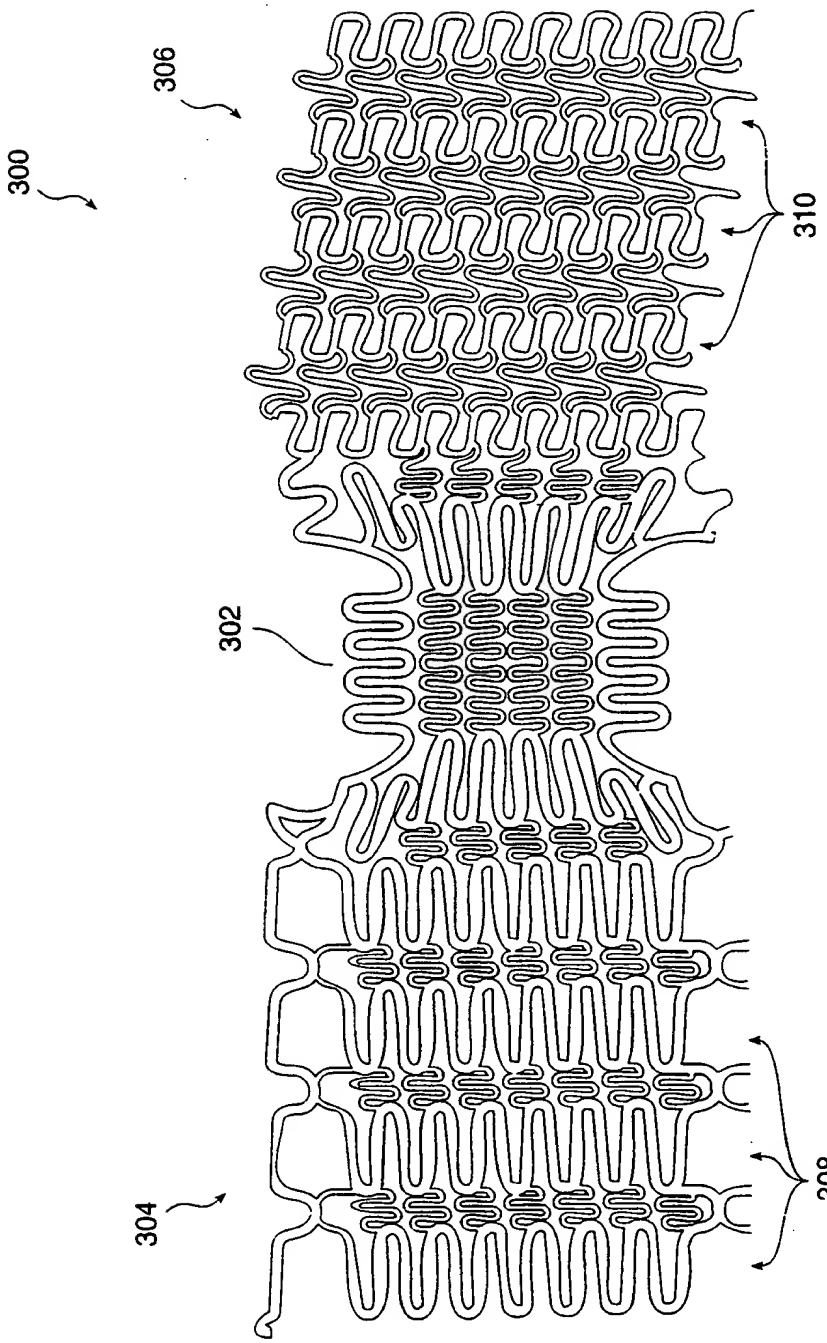


FIG. 12

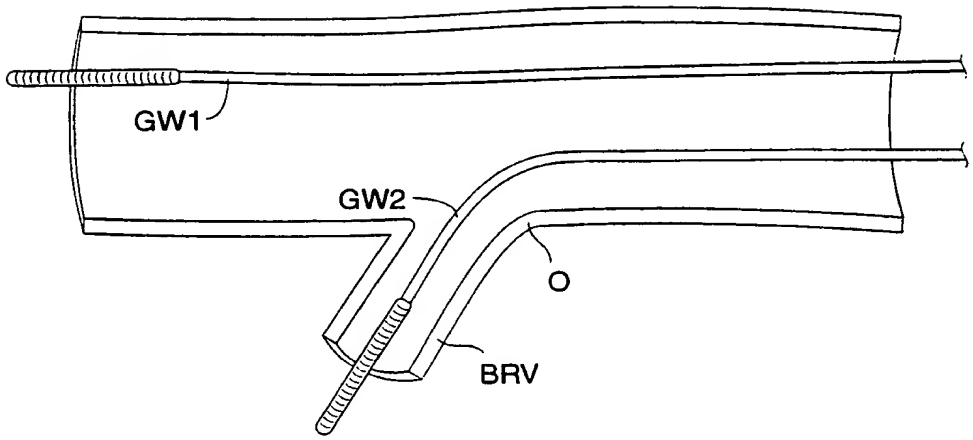


FIG. 13A

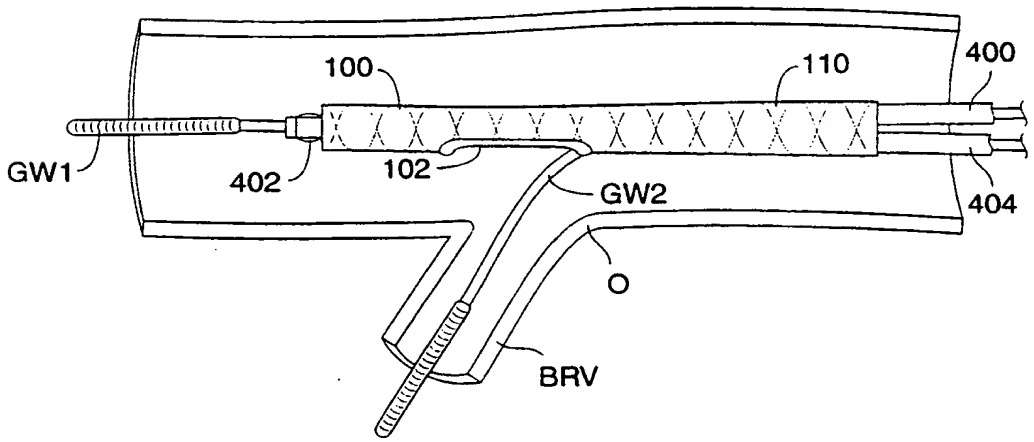


FIG. 13B

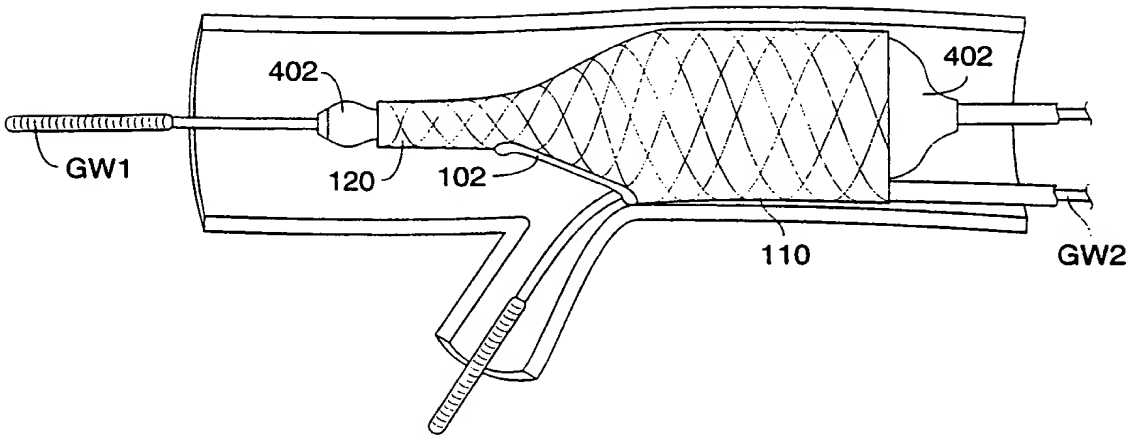


FIG. 13C

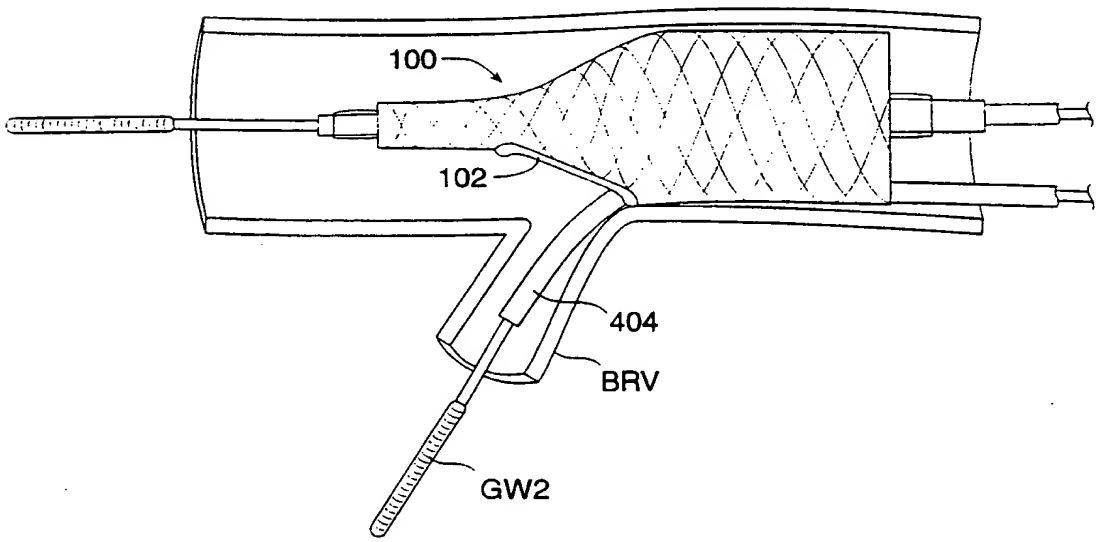


FIG. 13D

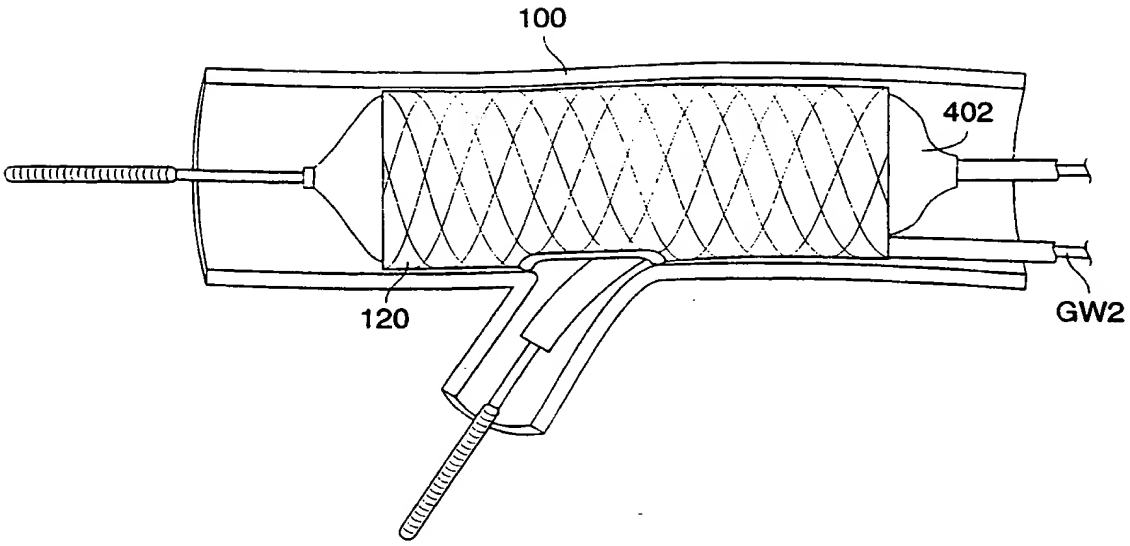


FIG. 13E

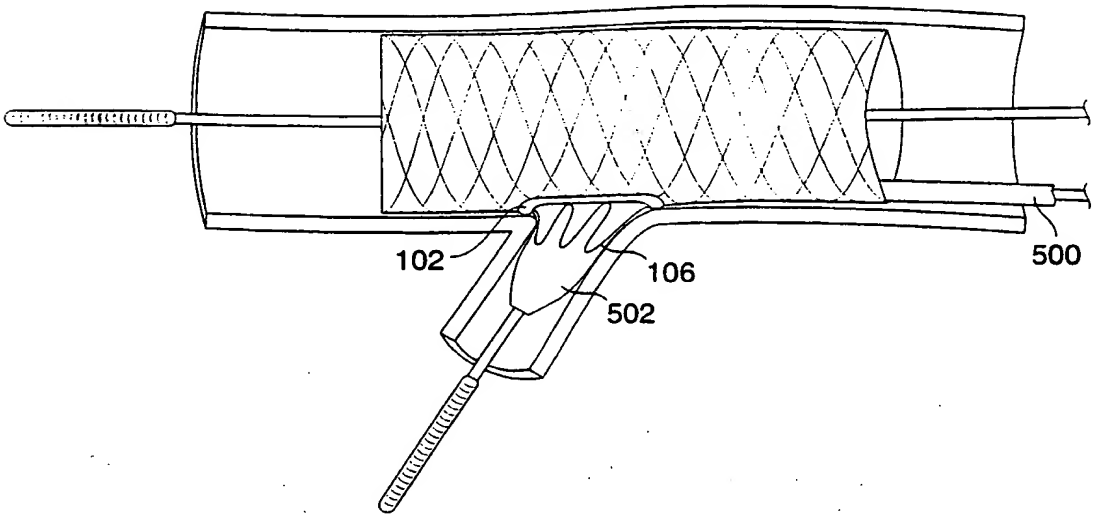


FIG. 13F

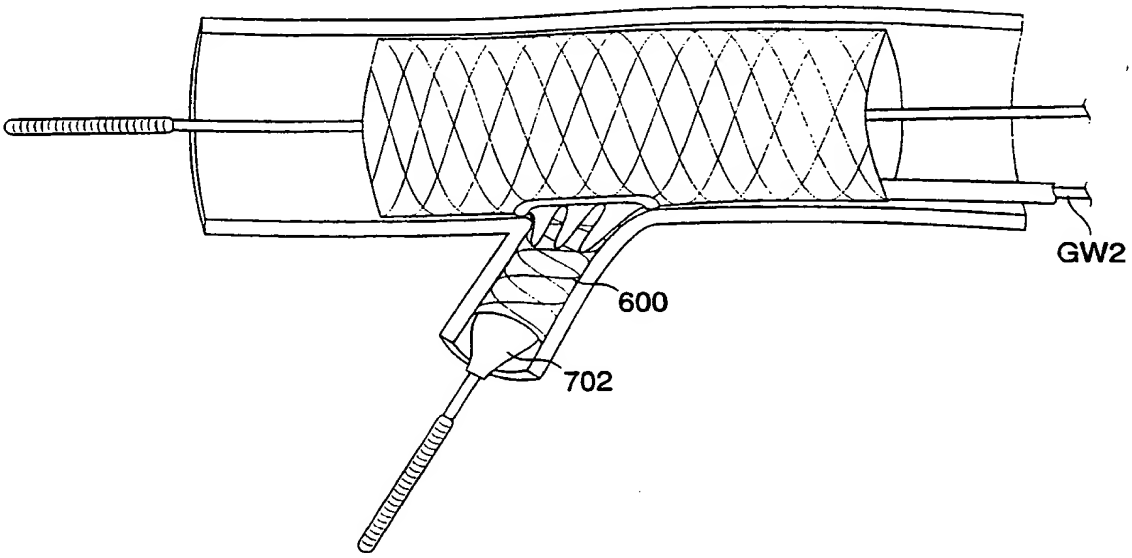


FIG. 13G

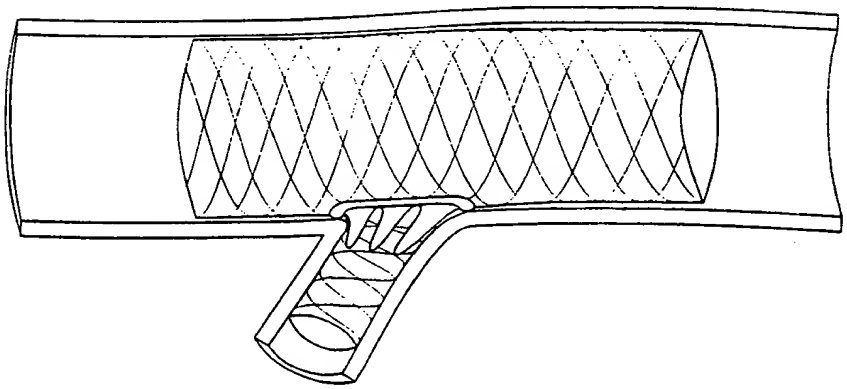


FIG. 13H

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/00835

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61F 2/06
US CL :623/1
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/191,194, 198; 623/1, 11

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	US 5,755,778 A (KLESHINSKI) 26 May 1998, entire document.	1-4
X	US 5,617,878 A (TAHERI) 08 April 1997, entire document.	1-3

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 01 MARCH 1999	Date of mailing of the international search report 22 MAR 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer PAUL PREBILIC Telephone No. (703) 308-2905

Form PCT/ISA/210 (second sheet)(July 1992)★

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/00835

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 5-10, 15, 19, 20
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

mark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

PATENT COOPERATION TREATY

TOWNSEND & TOWNSEND & CREW

From the INTERNATIONAL SEARCHING AUTHORITY

To: JAMES M. HESLIN
TOWNSEND AND TOWNSEND AND CREW LLP
TWO EMBARCADERO CENTER, 8TH FLOOR
SAN FRANCISCO, CALIFORNIA 94111-3834

99 MAR 26 AM 8:04 **PCT**

RECEIVED

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

Date of Mailing *(day/month/year)* 22 MAR 1999	
Applicant's or agent's file reference 19601-1-2PC	**FOR FURTHER ACTION** **See paragraphs 1 and 4 below**
International application No. PCT/US99/00835 ✓	International filing date *(day/month/year)* 13 JANUARY 1999 ✓
Applicant ADVANCED STENT TECHNOLOGIES, INC. ✓	

1. [X] The applicant is hereby notified that the international search report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. [ ] The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. [ ] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

[ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

[ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 *bis* 1 and 90 *bis* 3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer PAUL PREBILIC
Facsimile No. (703) 305-3230	Telephone No. (703) 308-2905

Form PCT/ISA/220 (January 1994)★ *(See notes on accompanying shee*

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 19601-1-2PC	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/US99/00835	International filing date *(day/month/year)* 13 JANUARY 1999	(Earliest) Priority Date *(day/month/year)* 14 JANUARY 1998
Applicant ADVANCED STENT TECHNOLOGIES, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. [X] **Certain claims were found unsearchable** (See Box I).

2. [ ] **Unity of invention is lacking** (See Box II).

3. [ ] The international application contains disclosure of a **nucleotide and/or amino acid sequence listing** and the international search was carried out on the basis of the sequence listing
   - [ ] filed with the international application.
   - [ ] furnished by the applicant separately from the international application,
     - [ ] but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
   - [ ] transcribed by this Authority.

4. With regard to the **title**,
   - [X] the text is approved as submitted by the applicant.
   - [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,
   - [ ] the text is approved as submitted by the applicant.
   - [X] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is:

   Figure No. 6g
   - [ ] as suggested by the applicant.
   - [X] because the applicant failed to suggest a figure.
   - [ ] because this figure better characterizes the invention.
   - [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/00835

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 5-10, 15, 19, 20
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

International application No.
PCT/US99/00835

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

The technical features mentioned in the Abstract do not include a reference sign between parentheses (PCT Rule 8.1(d)).

NEW ABSTRACT

The bifurcating double stent apparatus (10) of the present invention comprises a generally cylindrical main stent (12), a generally cylindrical branch stent (15), which are shown as fully dilated in a subject main vessel (8), and a subject branch vessel (7). The main stent (12) is deployed prior to the branch stent (15) which is then aligned with the side opening (16) of the main stent (12), and attached at that location.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/00835

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/06
US CL :623/1

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/191,194, 198; 623/1, 11

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	US 5,755,778 A (KLESHINSKI) 26 May 1998, entire document.	1-4
X	US 5,617,878 A (TAHERI) 08 April 1997, entire document.	1-3

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 01 MARCH 1999	Date of mailing of the international search report 22 MAR 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer PAUL PREBILIC Telephone No. (703) 308-2905